

PATENT Case No. 200021P

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: A.G. DAIFOTIS et al.

Serial No. 09/445,837

Filed: December 13, 1999

For: METHOD FOR INHIBITING BONE  
RESORPTIONArt Unit: 1615Examiner: T.J. Criares**RECEIVED**

AUG 20 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

TECH CENTER 1600/2900

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK &amp; CO., INC.

By Barbara Muller Date 8-14-03

**INFORMATION DISCLOSURE STATEMENT**

4. Except for Cite Nos. \_\_\_\_\_, copies of the references listed on the attached form are not enclosed because they have been submitted to or cited by the Office in a related application as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE
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upon which the instant application relies for an earlier filing date under 35 U.S.C. 120. Therefore, pursuant to 37 C.F.R. 1.98(d), copies of these references are not enclosed herewith. If this is inconvenient, additional copies will be submitted upon request.

5. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☒ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: J. Antonio Garcia-Rvias

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 42,567

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

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(732)594-1513

Date: August 14, 2003

Substitute for form 1449A/PTO

(Use as many sheets as necessary)

Sheet

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of

3

**COMPLETE IF KNOWN**

<b>Application Number</b>	09/445,837
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<b>Filing Date</b>	December 13, 1999
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<b>First Named Inventor</b>	A.G. Daifotis
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Group Art Unit	1615
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Examiner Name	T.J. Criares
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Attorney Docket Number	20002YP
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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

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SignatureDate  
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**INFORMATION DISCLOSURE****STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**COMPLETE IF KNOWN**

Application Number	09/445,837
Filing Date	December 13, 1999
First Named Inventor	A.G. Daifotis
Group Art Unit	1615
Examiner Name	T.J. Criares
Attorney Docket Number	20002YP

Sheet 2 of 3

**OTHER NON PATENT LITERATURE DOCUMENTS****RECEIVED**

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Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	99	Men's Osteoporosis Support Group, Vol. 1, Issue 2, 1 July 1997
	100	Rote List 1997, 66 023 (Fosamax)
	101	Reddy M.S. et al, J. Periodontol, 1995, Vol. 66(3), pp. 211-217, "Alendronate Treatment of Naturally-Occurring Periodontitis in Beagle Dogs".
	102	Fleisch H., "Bisphosphonates in Bone Disease from the Laboratory to the patient", 1995 (Book)
	103	Black D.M. et al., The Lancet, 1996, 348, pp. 1535-1541, "Randomised trial of effect of alendronate on risk of fracture in women with existing vertebral fractures".
	104	Affidavit of Gideon Rodan from validity trial of IL 94612 dated 17 Nov. 2000
	105	Merck & Co., Inc. - Instructions for Once Weekly Fosamax, January 2001
	106	Lombardi et al., Ann. Ital. Med. Int. 7, 1992, 3 Suppl., pp. 158-165, "Clinical trials with bisphosphonates"
	108	Reid et al, American Journal of Medicine, 1996, Vol. 101, pp. 341-348, "Biochemical and Radiologic Improvement in Paget's Disease of Bone Treated with Alendronate: A Randomized, Placebo-controlled Trial".
	109	Passeri et al, Bone and Mineral, 1991, Vol. 15, pp. 237-248, "Intermittent treatment with intravenous 4-amino-1-hydroxybutylidene-1,1-bisphosphonate (AHBuBP) in the therapy of postmenopausal osteoporosis".
	110	Devogelaer et al, Bone, 1996, Vol. 18(2), pp. 141-150, "Oral Alendronate Induces Progressive Increases in Bone Mass of the Spine, Hip, and Total Body Over 3 Years in Postmenopausal Women with Osteoporosis".
	111	Siris et al, J. Clin. Endo. Metab., 1996, Vol. 81(3), pp. 961-967, "Comparative Study of Alendronate Versus Etidronate for the Treatment of Paget's Disease of Bone".
	112	Toolan et al, J. Bone Min. Res., 1992, Vol. 3, pp. 1399-1406, "Effects of 4-Amino-1-Hydroxybutylidene Bisphosphonate on Bone Biomechanics in Rats".
	113	Balena et al, Bone, 1993, Vol. 14, pp. 499-504, "the Aminobisphosphonate Alendronate Inhibits Bone Loss Induced by Thyroid Hormone in the Rat Comparison Between Effects on Tibiae and Vertebrae".
	114	Fleisch et al, Hormone and Metabolic Research, Vol. 29 (1997), pp. 145-150, "Bisphosphonates: Mechanisms of Action and Clinical Use in Osteoporosis - An Update".

Examiner Signature

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**INFORMATION DISCLOSURE****STATEMENT BY APPLICANT***(use as many sheets as necessary)***COMPLETE IF KNOWN**

<b>Application Number</b>	09/445,837
<b>Filing Date</b>	December 13, 1999
<b>First Named Inventor</b>	A.G. Daifotis
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<b>Examiner Name</b>	T.J. Criares
<b>Attorney Docket Number</b>	20002YP

Sheet

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**OTHER NON PATENT LITERATURE DOCUMENTS**Examiner  
Initials\*Cite  
No.

Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.

115

E-mail communication of February 20, 1998 from Melton to DiCesare et al.

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